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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,058	02/08/2007	Rajesh Jain	U 015962-1	4104

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,058	JAIN ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,35-38 and 47-50* is/are pending in the application.

4a) Of the above claim(s) *48-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35-38 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's reply filed 10/22/2010 and supplemental response filed 10/25/2010 is acknowledged.

Applicant's election with traverse of Group I with traverse is acknowledged. The traversal is on the ground(s) that Lorenzo-Lamosa et al (Journal of Controlled Release, 1998) does not teach all the limitations of claim 33 as now amended. This is not found persuasive because, although Applicant has successfully amended the claim language around Lorenzo-Lamosa et al, the claimed invention still lacks a special technical feature. The common technical feature of the invention is a rapidly disintegrating oral controlled release pharmaceutical composition comprising at least one active ingredient, and a polymer system comprising of at least two polymers wherein at least one polymer is an acid insoluble methacrylic acid polymer and the other is a bioadhesive polycarbophil polymer, which retard the release of the active ingredient in the stomach while providing rapid release of the active ingredient in the pH above 5.5, optionally with other pharmaceutically acceptable excipients. This common technical feature cannot be a special technical feature, however, because it is not new. See claim rejections under 35 U.S.C. 103(a) given below.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 33 is objected to because of the following informalities: The phrase "...a polymer system comprising of at least two polymers..." is grammatically incorrect. The phrase should either read "...a polymer system comprising at least two polymers..." or "...a polymer system comprised of at least two polymers..." Furthermore, there is an underline between "wherein" and "at" in line 3. This appears to be a mistake. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-38 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 36, the recitation of derivative renders the claim indefinite. The recitation of "derivative" is indefinite because it is unclear how far removed the derivative can be from the parent compound with the derivative being an entirely different compound.

Regarding claim 37-38, these claims depend from claim 33. Claim 33 recites "a polymer system comprising of at least two polymers where at least one polymer is an acid insoluble methacrylic acid polymer and the other is a bioadhesive polymer". Claim 37 recites "wherein the polymer system comprises polymers selected from the group

consisting of..." and then recites polymers which include methacrylic acid polymer and polycarbophil in addition to other polymers. As methacrylic acid polymers and polycarbophil are required components of claim 33, it is unclear how in claim 37 they can be chosen from a list of other polymers. It is unclear if the polymers disclosed in claim 37 are meant to be in addition to the required polymers of claim 33 (methacrylic acid polymer and polycarbophil) or instead of them. Claim 38 recites "...wherein the acid insoluble polymer is selected from..." and then recites methacrylic acid polymer among other options. As claim 33 requires the acid insoluble polymer to be methacrylic acid polymer, it is unclear how claim 38 could give further options for what the acid insoluble polymer can be. Are the polymers in claim 38 meant to be further acid insoluble polymers added in addition to the methacrylic acid polymer of claim 33?

Regarding claim 47, the phrase "wherein the ratio of methacrylic acid and polycarbophil is 10:1 to 1:10 by weight of the composition" is unclear. Does this phrase mean the ratio of methacrylic acid to polycarbophil is 10:1 to 1:10 by weight? Such a reading is logical, except the recitation "by weight of the composition" implies that the total composition is part of the ratio. Does the above phrase then mean that the combined weight of methacrylic acid and polycarbophil to the total composition is 10:1 to 1:10? This reading is consistent with the phrase, but is illogical because the parts of a total composition cannot weigh more than the total composition itself. If Applicant is intending to claim that the weight ratio of methacrylic acid polymer to polycarbophil is 10:1 to 1:10, the Examiner recommends reciting "...wherein the weight ratio of methacrylic acid polymer to polycarbophil is 10:1 to 1:10." or similar language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33, 35, 37-38, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,614,222 ('222). '222 discloses a rapidly disintegrating oral

controlled release pharmaceutical composition comprising amoxicillin trihydrate and a matrix material present in a core, wherein the core is coated with an enteric polymer. The matrix material may be a bioadhesive polycarbophil polymer (col 5, line 15) and the enteric polymer may be Eudragit L-100 (an acid insoluble methacrylic acid polymer) (col 5, line 57). The enteric coating may be 30% (col 6, line 15). The polymer system retards the release of the active ingredient in the stomach while providing rapid release in pH ranges above 5.5 (col 5, lines 22-32). Other pharmaceutically acceptable excipients may also be present (examples).

'222 fails to disclose a specific combination of bioadhesive polycarbophil polymer and Eudragit L-100.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to prepare a composition according to '222 with bioadhesive polycarbophil polymer as the matrix material and Eudragit L-100 as the enteric coating material. The rationale for this is that '222 teaches that bioadhesive polycarbophil polymer may be the matrix material and Eudragit L-100 may be the enteric coating material, and accordingly this combination is one of the possible combinations suggested by '222. It would have been further obvious to find the weight ratio of methacrylic acid polymer to polycarbophil of 10:1 to 1:10, through routine experimentation, to optimize the release of the drug. '222 gives sufficient guidance to this end, as it teaches the enteric coating may be 30% of the composition, which implies that the remaining 70% is the matrix material and drug (or 30 methacrylic acid polymer to ~70 polycarbophil, which is equivalent to 1:~2.3). "'[W]here the general conditions of

a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

Claims 33, 35-38, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,614,222 ('222) in view of US 6979735 ('735). The relevant portions of '222 are given above.

'222 fails to disclose adding a second active ingredient listed in instant claim 36.

'735 teaches that clavulanic acid is often added to beta-lactam antibiotics, such as amoxicillin, to enhance the effectiveness of the drug (col 1, lines 11-29).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to add clavulanic acid to the composition of '222 to improve the anti-microbial effectiveness of amoxicillin. It is common in the pharmaceutical arts to add beta-lactamase inhibitors, such as clavulanic acid, to beta-lactam antibiotics, such as amoxicillin, because the beta lactamase inhibitors inhibit the microbe's beta-lactamases (i.e., the inhibitor hinders the microbe's resistance to the drug). Thus, it would be obvious to add clavulanic acid to the composition of '222 to enhance the effectiveness of amoxicillin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

November 1, 2010